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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/500,747	02/09/00	GOKHALE	R 300622004600

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EXAMINER	
KERR,K	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 10/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/500,747	Applicant(s) GOKHALE ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication app ars on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *23-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application Status

1. The previous Office action was a written restriction requirement (Paper No. 6 mailed June 11, 2001). Applicants responded to said action with an election (Paper No. 7) and a preliminary amendment (Paper No. 8) canceling all the previously pending claims and adding new Claims 23-44. Due to the different presentation of the claimed subject matter, the previous written restriction requirement is no longer pertinent; Applicants' traversal of the previous restriction requirement (Paper No. 7) is moot.

The instant Office action is a supplemental written restriction requirement that considers new Claims 23-44.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 23-39, drawn to hybrid polyketide synthase enzymes, classified in class 435, subclass 183.

II. Claims 40-42, drawn to nucleic acid sequences encoding hybrid polyketide synthase enzymes and methods of making said enzymes, classified in class 435, subclass 183.

III. Claims 43-44, drawn to methods of making polyketides, classified in class 435, subclass 64.

3. The inventions are distinct, each from the other because of the following reasons:

The DNA of Group II is related to the enzymes of Group I by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because they have distinct structural features and different uses – the DNA is useful for making the enzymes and the enzymes are useful in making polyketides and catalyzing other reactions. Moreover, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups I and II are patentably distinct. While these two Groups are identically classified, a search of Group I would not be co-extensive with Group II in the non-patent literature since distinct structural databases (DNA or protein) must be searched. Thus, combining these patentably distinct inventions would result in a search burden on the Examiner.

Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the enzymes can be used in materially distinct processes such as in the production of antibodies *in vivo*. Thus, Groups I and III are patentably distinct. These Groups are classified differently; a search of more than one class/subclass would constitute a search burden on the Examiner.

Group II, drawn to nucleic acids, and Group III, drawn to methods of making polyketides using polyketide synthases, are related because the nucleic acids encode the enzymes used in the methods. While the nucleic acids are useful in the production of the polypeptides for use in the

methods of making polyketides, the nucleic acids themselves are not necessary to practice the methods. Therefore, the Groups II and III are patentably distinct. These Groups are classified differently; a search of more than one class/subclass would constitute a search burden on the Examiner.

Notice of Possible Rejoinder

4. The Examiner notes that if claims in Group I are found directed to an allowable product, then claims in Group III, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process in Group III would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. A telephone call was made to Dr. Brenda Wallach on October 12, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. Applicants must respond to the instant Office action with an election of Group to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
October 13, 2001